

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ENDO PHARMACEUTICALS INC. and
STRAKAN INTERNATIONAL S.á r.l.,

Plaintiffs,

v.

WATSON LABORATORIES, INC.,

Defendant.

Case No. 2:13-CV-192-JRG

MEMORANDUM OPINION AND ORDER

Before the Court are Plaintiffs' Endo Pharmaceutical Inc. and Strakan International S.á r.l. Opening Claim Construction Brief (Dkt. No. 58), Defendant's Watson Laboratories, Inc.'s Responsive Claim Construction Brief (Dkt. No. 62), and Plaintiffs' reply (Dkt. No. 63), concerning U.S. Patent No. 6,319,913 ("the '913 patent").

The Court held a hearing on June 6, 2014.

I. BACKGROUND

This case concerns Defendant's alleged infringement of the '913 patent, as well as U.S. Patent No. 6,579,865.¹ Defendants have filed an Abbreviated New Drug Application ("ANDA") seeking approval from the United States Food and Drug Administration to market a generic version of Plaintiff's Fortesta® product prior to the expiration of these two patents. The '913 patent is titled "Penetration Enhancing and Irritation Reducing Systems." It generally concerns methods of treatment with a topically or systemically active drug by topically administering a composition comprising a drug such as testosterone and a penetration enhancing system, resulting in increased penetration of the drug through the skin and/or reduced skin inflammation.

Claims 1, 5 and 19 contain the terms to be construed. Claim 1² recites:

1. A method for administering a topically or systemically active agent *with increased penetration*, said method comprising: topically administering to a mammal a composition comprising:

a) an active agent having a concentration of about 0.1% to about 2%, wherein said active agent is a member selected from the group consisting of testosterone, estradiol, derivatives thereof, and mixtures thereof;

b) a penetration-enhancing system consisting essentially of (i) a membrane fluidizer comprising oleic acid; (ii) a C₁-C₄ alcohol; and (iii) a glycol

 said composition having a pH value of between about 4 to about 8, thereby administering a topically or systemically active *with increased penetration*.

Claim 5 reads:

5. A method *for reducing inflammation associated with topical application of a topically or systemically active agent*, said method comprising: topically administering to a mammal a composition comprising:

a) an active agent having a concentration of about 0.1% to about 2%, wherein said active agent is a member selected from the group consisting of testosterone, estradiol, derivatives thereof, and mixtures thereof;

b) a penetration-enhancing system consisting essentially of (i) a membrane fluidizer comprising oleic acid; (ii) a C₁-C₄ alcohol; and (iii) a glycol

 said composition having a pH value of between about 4 to about 8, *thereby reducing inflammation associated with at topical application of a topically or systemically active agent*.

¹ The parties have not identified any terms in the '865 patent for construction by the Court.

² Claim 19 is similar to claim 1, but limits the active agent to testosterone or a derivative thereof. Accordingly, in the interest of brevity, the Court has not quoted claim 19 below.

The parties' dispute centers on the meaning of italicized terms.

II. LEGAL PRINCIPLES

It is understood that “[a] claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using or selling the protected invention.” *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999). Claim construction is clearly an issue of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996).

To ascertain the meaning of claims, courts look to three primary sources: the claims, the specification, and the prosecution history. *Markman*, 52 F.3d at 979. The specification must contain a written description of the invention that enables one of ordinary skill in the art to make and use the invention. *Id.* A patent’s claims must be read in view of the specification, of which they are a part. *Id.* For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. *Id.* “One purpose for examining the specification is to determine if the patentee has limited the scope of the claims.” *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed. Cir. 2000).

Nonetheless, it is the function of the claims, not the specification, to set forth the limits of the patentee’s invention. Otherwise, there would be no need for claims. *SRI Int’l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc). The patentee is free to be his own lexicographer, but any special definition given to a word must be clearly set forth in the specification. *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388 (Fed. Cir. 1992). Although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim

language is broader than the embodiments. *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994).

This Court’s claim construction analysis is substantially guided by the Federal Circuit’s decision in *Phillips v. AWH Corporation*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). In *Phillips*, the court set forth several guideposts that courts should follow when construing claims. In particular, the court reiterated that “the claims of a patent define the invention to which the patentee is entitled the right to exclude.” 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To that end, the words used in a claim are generally given their ordinary and customary meaning. *Id.* The ordinary and customary meaning of a claim term “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1313. This principle of patent law flows naturally from the recognition that inventors are usually persons who are skilled in the field of the invention and that patents are addressed to, and intended to be read by, others skilled in the particular art. *Id.*

Despite the importance of claim terms, *Phillips* made clear that “the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.* Although the claims themselves may provide guidance as to the meaning of particular terms, those terms are part of “a fully integrated written instrument.” *Id.* at 1315 (quoting *Markman*, 52 F.3d at 978). Thus, the *Phillips* court emphasized the specification as being the primary basis for construing the claims. *Id.* at 1314-17. As the Supreme Court stated long ago, “in case of doubt or ambiguity it is proper in all cases to refer back to the descriptive portions of the specification to aid in solving the doubt or in ascertaining the true intent and

meaning of the language employed in the claims.” *Bates v. Coe*, 98 U.S. 31, 38 (1878). In addressing the role of the specification, the *Phillips* court quoted with approval its earlier observations from *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998):

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.

Phillips, 415 F.3d at 1316. Consequently, *Phillips* emphasized the important role the specification plays in the claim construction process.

The prosecution history also continues to play an important role in claim interpretation. Like the specification, the prosecution history helps to demonstrate how the inventor and the Patent and Trademark Office (“PTO”) understood the patent. *Id.* at 1317. Because the file history, however, “represents an ongoing negotiation between the PTO and the applicant,” it may lack the clarity of the specification and thus be less useful in claim construction proceedings. *Id.* Nevertheless, the prosecution history is intrinsic evidence that is relevant to the determination of how the inventor understood the invention and whether the inventor limited the invention during prosecution by narrowing the scope of the claims. *Id.*; see *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004) (noting that “a patentee’s statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation”).

Phillips rejected any claim construction approach that sacrificed the intrinsic record in favor of extrinsic evidence, such as dictionary definitions or expert testimony. The *en banc* court condemned the suggestion made by *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193 (Fed. Cir. 2002), that a court should discern the ordinary meaning of the claim terms (through dictionaries or otherwise) before resorting to the specification for certain limited purposes.

Phillips, 415 F.3d at 1319-24. According to *Phillips*, reliance on dictionary definitions at the expense of the specification had the effect of “focus[ing] the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent.” *Id.* at 1321. *Phillips* emphasized that the patent system is based on the proposition that the claims cover only the invented subject matter. *Id.*

Phillips does not preclude all uses of dictionaries in claim construction proceedings. Instead, the court assigned dictionaries a role subordinate to the intrinsic record. In doing so, the court emphasized that claim construction issues are not resolved by any magic formula. The court did not impose any particular sequence of steps for a court to follow when it considers disputed claim language. *Id.* at 1323-25. Rather, *Phillips* held that a court must attach the appropriate weight to the intrinsic sources offered in support of a proposed claim construction, bearing in mind the general rule that the claims measure the scope of the patent grant.

III. CONSTRUCTION OF DISPUTED TERMS

a. “with increased penetration”

Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
To the extent any construction is necessary, “with increased penetration as compared to a formulation that lacks a penetration enhancing system”	Indefinite

(Dkt. No. 54-1, 3/14/14 Joint Claim Construction and Prehearing Statement, Ex. A at 1).

i. The Parties’ Positions

The parties’ dispute centers on the meaning of the words “with increased penetration” as found in both the preamble to claims 1 and 19, as well as the last clause of both claims.

Plaintiffs argue that no construction of the term is required, and that one skilled in the art would readily understand the term. In other words, according to Plaintiffs “the language of the claims themselves makes clear that the inclusion of a ‘penetration-enhancing system’ in the formulation results in the active agent being administered ‘with increased penetration.’” (Dkt. No. 62 at 1). Plaintiffs submit that it should, therefore, be accorded its plain and ordinary meaning. To the extent that any construction is necessary, Plaintiffs contend that the term should be construed as “with increased penetration as compared to a formulation that lacks a penetration enhancing system.”

Defendant submits that the term “with increased penetration” is indefinite and therefore renders these claims invalid. According to Defendant, the words “with increased penetration” are “words of degree” for which the Court must determine whether the patent provides a standard for determining that degree, citing *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005). Defendant submits that the ‘913 patent and prosecution history fail

to provide such a standard, and in fact, provide conflicting comparisons that render the term indefinite.

ii. Analysis

The term “with increased penetration” is found in both the preamble to claims 1 and 19, and in the last clause of those claims, which reads: “thereby administering a topically or systemically active agent with increased penetration.” As an initial matter, the Court must first determine whether the claim preamble and “thereby” clause are limitations on the claims that require construction.

While Defendant argues that all terms in a claim must be given effect, Dkt. No 62 at 18-19, there are at least two important exceptions to any such rule. First, as Defendant itself admits, language in a claim preamble is generally not considered claim limiting. (Dkt. No. 62 at 20). Second, language in a “whereby,” or as here, a “thereby” clause, in a method claim is given no weight when it merely states the intended result of a method step or steps. *Minton v. National Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381 (Fed. Cir. 2003).

Because the disputed term appears in the preamble to claim 1, the Court first determines whether that term, and the preamble in which it appears, is in fact a separate limitation on the claim. The language in a claim preamble is generally not limiting. *See Symantec Corp. v. Computer Associates Int'l Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008). A preamble is a limitation on a claim “if it recites essential structure or steps, or if it is ‘necessary to give life, meaning, and vitality’ to the claim.” *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed.Cir.2002) (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed.Cir.1999)). A preamble is not limiting, however, if the claims define a structurally

complete invention in the claim body and the preamble only states a purpose or intended use for the invention. *Id.*

The Court, having considered the evidence before it, determines that the preamble in claims 1 and 19 is not a limitation on the claims. As noted above, a preamble is not limiting where the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the method steps of the claim. *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434 (Fed.Cir.2000). Here, claims 1 and 19 set forth structurally complete inventions without reference to the preamble. The claims define a method comprising topically administering to a mammal a composition comprising an active agent and the defined penetration enhancing system. Deletion of the preamble does not affect the method steps of the claim.

Moreover, preamble language that simply sets forth the benefits or features of a claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant. *STX, LLC v. Brine, Inc.*, 211 F.3d 588, 591 (Fed.Cir.2000) (preamble stating that invention provides “improved playing and handling characteristics” is not a limitation). *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed.Cir.2001) is particularly instructive. There, the patent claimed: “A method for reducing hematologic toxicity in a cancer patient undergoing [t]axol treatment comprising parenterally administering to said patient an antineoplastically effective amount of about 135–175 mg/m² taxol over a period of about three hours.” *Id.* at 1372 (emphasis added). According to the Federal Circuit:

We discern no error in the district court's interpretation of that language as non-limiting, and merely expressing a purpose of reducing hematologic toxicity relative to the toxicity experienced by a patient undergoing a twenty-four-hour infusion. The steps of the three-hour infusion method are performed in the same

way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim. *See, e.g., In re Hirao*, 535 F.2d 67, 70, 190 USPQ 15, 16–17 (CCPA 1976) (holding that the preamble was non-limiting because it merely recited the purpose of the process, which was fully set forth in the body of the claim).

Id. at 1375. Similarly here, the preamble simply states the purpose of the method, to increase penetration of the active agent. The claimed process steps are fully set forth in the body of claims 1 and 19.

The patent specification supports this conclusion as well. For example, the “SUMMARY OF THE INVENTION,” states that the “penetration enhancing system of the present invention effectively enhances delivery of transdermally and/or topically active substances, while surprisingly reducing skin irritation caused by the application of irritating substances to the skin.” Dkt. No. 58, Ex. 1 at col. 2, lines 33-37. Similarly, the patent states that the “penetration enhancing system of the present invention increases transdermal and topical drug delivery while decreasing skin irritation, thereby allowing high levels of drug delivery to be achieved without causing unacceptable adverse skin reactions.” *Id.* at col. 3, lines 17-21. Thus, the patent specification likewise supports the conclusion that the preamble simply sets for the purpose of the claimed method.

The Court has also considered the prosecution history to determine if the preamble language was relied on to distinguish the claimed invention from the prior art. *Catalina Marketing*, 289 F.3d at 808-809. While a closer question, the Court finds no clear reliance on the preamble for the purposes of distinguishing the prior art.

The claims that ultimately resulted in claims 1 and 19 were amended on numerous occasions. In an amendment presented on February 15, 2000, the term “with increased

penetration” first appeared in the preamble to then claim 37 (which issued as claim 1), along with an amendment limiting the set of active agents to “a member selected from the group consisting of a mammalian hormone, a hormone mimetic, or a derivative thereof.” (Dkt. No. 62, Ex. 4 at 9875. The applicants explained that the “function of the pH change in the instant application is to *enhance* penetration.” *Id.* at 9880 (emphasis in original). As Defendant recognizes, the applicants relied on the claimed pH range as the “critical limitation” in distinguishing the prior art. Dkt. No. 62 at 7.

Following this amendment, the patent examiner continued to reject the claims, and at a meeting with the applicants, it was agreed that narrower claims should be filed. Dkt. No. 62, Ex. 4 at 9893. The applicants then filed an amendment to claim 37, reading:³

A method for administering a topically or systemically active agent with increased penetration, said method comprising: topically administering to said mammal a composition comprising:

- a) an active agent wherein said active agent is a member selected from the group consisting of a mammalian hormone [,a hormone mimetic] or a derivative thereof;
- b) a penetration-enhancing system comprising: (i) a membrane fluidizer comprising oleic acid; (ii) a C₁-C₄ alcohol; and (iii) a glycol, said composition having a pH value of between about 4 to about 8, thereby administering a topically or systemically active agent with increased penetration.

The applicants explained that they had surprisingly discovered that the “methods of the present invention having a composition with optimum pH values give unexpectedly high permeation of active ingredients.” *Id.* at 9899. Thereafter, the applicants and the patent examiner made a number of other narrowing amendments until ultimately claims 1 and 19 issued in their current form. The applicants again explained that “the function of the pH change in the instant application is to enhance penetration.” *Id.* at 9954-55. Enhanced penetration was repeatedly described as a “superior,” “surprising,” and “beneficial property.” *Id.* at 9957, 9965 Thus, the

³ Underlining represents additions to the claim, brackets deletions from the claim.

prosecution history makes it clear that “with increased penetration” is the purpose or function of the method of administration.

While “clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation,” *Catalina Marketing*, 289 F.3d at 808-809, the Court is unable to conclude that there was such clear reliance here. Although the applicants stressed the “superior,” “surprising,” and “beneficial properties” resulting from the claimed invention, those properties flow from the practice of the claimed method steps. Moreover, the applicants relied on the specific combination of elements (the specified active ingredients at the enumerated concentrations in a composition together with the penetration enhancing system in the specific pH range) to distinguish the prior art. *See* Dkt. No. 62, Ex. 4 at 9951-57). So too did the patent examiner, as shown by the examiner’s statement of reasons for allowance. *See Id.* at 9996-97. That the applicants had long earlier added claim language alleging the specific benefit of increased penetration does not alter this analysis. While the applicants did cite to the allegedly superior and surprising property of enhanced penetration that results from the claimed method, that property is, as stated above, the intended result of the claimed process. Such statements did not transform the preamble language into a claim limitation requiring construction. *Bristol-Myers*, 246 F.3d at 1375.

Dependence on a particular disputed preamble phrase for antecedent basis may also limit claim scope if it indicates a reliance on both the preamble and claim body to define the claimed invention. *Catalina Marketing*, 289 F.3d at 808. However, there is no reliance here on the preamble phrase for antecedent basis. While the use of the same words in the “thereby” clause might be argued to indicate such reliance, as explained below, the Court similarly accords no limiting weight to the “thereby” clause and its use of the term “with increased penetration.”

A “whereby,” or in this case a “thereby” clause, in a method claim is “not given weight when it simply expresses the intended result of a process step.” *Minton*, 336 F.3d at 1381. The term at issue in *Minton* was “traded efficiently.” According to the Federal Circuit, the “term ‘efficiently’ on its face does not inform the mechanics of how the trade is executed, and nothing in the specification or the prosecution history suggests otherwise. Rather, the term ‘efficiently’ is a laudatory one characterizing the result of the executing step.” *Id.* Similarly here, the “thereby” clause simply characterizes the result of practicing the claimed method steps.

Bristol-Myers is again instructive. One of the terms at issue in that case was “an antineoplastically effective amount,” of taxol, a drug for treating certain types of tumors. The prior art had disclosed administering the same dosages of taxol to patients with the same tumor types as claimed, but did not report any anti-tumor (anti-neoplastic) effectiveness. The patentee argued that the term “antineoplastically effective amount” required that the dosage have an actual anti-tumor effect in a particular patient. The Federal Circuit rejected that argument, stating that the phrase was simply an expression of intended result that did not affect, or further limit, the express dosages set forth in the claims. Similarly, both the preamble and the “therein” clause here are simply expressions of intended result that follow from practicing the steps of the method, administering the claimed composition.⁴ *Bristol-Myers*, 246 F.3d at 1375. *See also Syntex (USA) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1378 (Fed. Cir. 2005) (“We agree with the district court that the term ‘in a stabilizing amount’ simply describes the intended result of using the weight to volume ratios recited in the claims”); *Texas Instruments Inc. v. U.S. Intern. Trade*

⁴ As cited by Defendants, Plaintiffs’ expert Dr. Guy agrees. In his deposition, Dr. Guy testified:

Q: So my question is, if the composition has those three elements of the penetration enhancing system, is it your opinion that the composition will necessarily then meet the limitation at the end of claim one that says “with increased penetration.”

A: Yes.

Com'n, 988 F.2d 1165 (Fed. Cir. 1993) ("The 'whereby/to preclude' clauses of claims 12, 14 and 17 merely describe the result of arranging the components of the claims in the manner recited in the claims: the fluid does not directly engage the device and the electrical connection means because the gate through which the fluid enters is remote from them; the conductors are secured against appreciable displacement by the fluid because they are clamped in notches by the upper and lower halves of the mold die. Therefore, the Commission correctly determined that the 'whereby/to preclude' clauses do not contain any limitations not inherent to the process found in claims 12, 14 and 17."); *Plant Equipment, Inc. v. Intrado, Inc.*, 2012 WL 1468594 *15 n.19 (E.D. Tex. Apr. 27, 2012) (following *Minton*); *Ideal Instruments, Inc. v. Rivard Instruments, Inc.*, 498 F.Supp.2d 1131, 1208-1210 (N.D. Iowa 2007) (finding that "whereby," "such that," or "so that" clauses were "laudatory" clauses characterizing the result of the method step and as such did not constitute claim limitations); *Prometheus Laboratories Inc. v. Roxane Laboratories, Inc.*, 2013 WL 5333033 *5-6 (D.N.J. Sep. 23, 2013) ("wherein said female IBS patient experiences improvement in stool consistency, bowel movement frequency and the proportion of days with urgency while being treated with alosetron" is laudatory statement of no weight).

Accordingly, the Court holds that the term "with increased penetration," found in the preamble and "thereby" clause of claims 1 and 19 is simply a statement of intended result or purpose, to be accorded no weight, and therefore, no construction of the term is necessary. While Defendant claims that this would result in a "tautology—if a composition has a 'penetration-enhancing system,' the active agent is 'administered with increased penetration,'" that is precisely what the law requires here. A term that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. See, e.g., *Texas*

Instruments, 988 F.2d at 1172. Defendant’s argument that the claim is indefinite and invalid is therefore rejected.

The Court also rejects Defendant’s argument that “with increased penetration” is a term of “degree,” and therefore that the ‘913 patent must provide some standard for measuring that degree. Words of degree⁵ can be problematic where they require a subjective inquiry. For that reason the Federal Circuit has required that a patent containing claims requiring such a subjective inquiry provide an “objective anchor” that identifies the bounds of the claim. *See, e.g.*, *Datamize*, 417 F.3d at 1350. But here, there is nothing subjective about the words “with increased penetration.” One skilled in the art would understand that any amount of increase in penetration would meet this language, if it constituted a separate limitation of the claims. *See, e.g.*, *Iovate Health Sciences, Inc. v. Allmax Nutrition, Inc.*, 639 F.Supp.2d 115, 120 (2009) (“For example, a 0.01% increase may not be statistically significant but is, nevertheless, an increase.”). *See also Abbott Laboratories v. Sandoz, Inc.*, 529 F. Supp. 2d 183, 912 (N.D. Ill. 2007) (“‘Lower’ simply means less than.””). There is no basis for the Court to find that the words “with increased penetration” are “words of degree” and the Court rejects Defendant’s argument to the contrary.

Indefiniteness is an invalidity defense that must be proven by clear and convincing evidence. *See, e.g.*, *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1347 (Fed. Cir. 2007). A claim is indefinite if the “claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the

⁵ The courts have found words such as “substantially equal to,” *see Seattle Box Co. v. Indus. Crafting & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 184); “about,” *see BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1372–73 (Fed.Cir.2003), “substantial absence,” *see Exxon Research & Eng’g Co. v. United States*, 265 F.3d 1371, 1380–81 (Fed. Cir. 2001); “readily installed,” *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010); and “aesthetically pleasing,” *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005) to be words of degree. It is readily understandable that these terms would all require some objective anchor, as those terms all have some degree of subjectivity to them. Here, on the contrary, the word “increased” does not require a subjective inquiry. It is an objective term.

scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. __ (2014), No. 13-369, slip op. at 1 (June 2, 2014). During oral argument, Defendant admitted that its indefiniteness argument failed if the Court rejected its “words of degree” argument. Transcript at 55-56. The Court having rejected Defendant’s argument, finds that Defendant has failed to establish by clear and convincing evidence that the term “with increased penetration,” and therefore the claims in which the term appears, are invalid as indefinite.

b. “reducing inflammation associated with a topical application of a topically or systemically active agent”

Plaintiff’s Proposed Construction	Defendants’ Proposed Construction
To the extent any construction is necessary, “reducing inflammation associated with topical application of a topically or systemically active agent as compared to an identical formulation wherein the formulation contains oleyl alcohol instead of oleic acid.”	Indefinite.

(Dkt. No. 103-1, 5/3/13 Updated Joint Claim Construction and Prehearing Statement, Ex. A at 20-22).

i. The Parties’ Positions

The parties’ dispute centers on the meaning of the words “reducing inflammation” within this clause, as found in both the preamble and last clause of claim 5.

Plaintiffs argue that no construction of the term is required, and that one skilled in the art would readily understand the term. Plaintiffs submit that it should, therefore, be accorded its plain and ordinary meaning. Plaintiffs also assert that the “reducing inflammation” limitation simply recites the result flowing from the claimed method. To the extent that any construction is necessary, Plaintiffs contend that the term should be construed as requiring a comparison with an identical formulation in which oleyl alcohol is substituted for the oleic acid in the claimed formulation.

Defendant submits that the term “reducing inflammation” is indefinite and therefore renders these claims invalid. As above, Defendant asserts that the words “reducing inflammation” within the clause to be construed are “words of degree.” Defendant again asserts that the patent must provide an objective standard for determining that degree, citing *Datamize*, 417 F.3d at 1351 (Fed. Cir. 2005). Defendant argues that the ‘913 patent and prosecution history fail to provide such a standard, and in fact, provide conflicting comparisons that render the term indefinite.

ii. Analysis

As with the term “with increased penetration,” the clause to be construed appears in both the claim preamble and in a “thereby” clause appearing at the end of the claim. For the same reasons stated above regarding “with increased penetration,” the Court holds that no construction of the term “reducing inflammation associated with a topical application of a topically or a systemically active agent” is necessary.

First, the preamble to claim 5 is not limiting because the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the method steps of the claim. *IMS Tech.*, 206 F.3d at 1434. Additionally, preamble language merely setting forth the benefits or features of a claimed invention does not limit the claim scope. See, e.g., *STX, LLC*, 211 F.3d at 591 (Fed.Cir.2000); *Bristol-Myers Squibb*, 246 F.3d at 1375. The preamble here states the purpose of the method, to reduce inflammation associated with topical application of a drug.

As described above, the patent specification also supports this conclusion. So too does the prosecution history. First, claim 42 (which issued as claim 5) contained the preamble clause at the time it was presented. (Dkt. No. 62-4 at 9718). Moreover, the prosecution history

repeatedly describes the reduction of inflammation as a result or property flowing from the use of the claimed method. *Id.* at 9952, 9954-55, 9957, 9965. Reliance on the alleged superior and surprising benefit did not make the preamble a limitation. *See Bristol-Myers*, 246 F.3d at 1375.

The Court also finds that there is no reliance on the preamble phrase for antecedent basis for the same language appearing in the “thereby” clause. As above, the Court finds that the “thereby” clause is to be given no weight here, since it simply states the intended result of a process step. *Minton*, 336 F.3d at 1373; *Bristol-Myers*, 246 F.3d at 1375; *Syntex*, 407 F.3d at 1378; *Texas Instruments*, 988 F.2d at 1172. And, while the “thereby” clause was added during prosecution, (Dkt. No. 62-4 at 9897) it was made at the same time as other amendments to the claim, and further amendments were required before allowance. *See id.* at 9949.

Accordingly, the Court holds that the preamble and “thereby” clause of claim 5 is simply a statement of intended result or purpose, to be accorded no weight, and therefore, no construction of the term is necessary. As such, Defendant’s argument that the claim is indefinite and invalid must fail. A clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. *See, e.g., Texas Instruments*, 988 F.2d at 1172. Moreover, the Court also rejects Defendant’s argument that the words “reducing inflammation” are “words of degree,” and accordingly Defendant’s indefiniteness argument falls for this reason as well.⁶ Any amount of reduction would meet this limitation if it were a separate limitation of the claims. *See, e.g., Iovate Health Sciences*, 639 F.Supp.2d at 120. The term “reducing inflammation” provides a sufficient objective standard for one skilled in the art to understand the scope of the claim. Defendant has not established by clear and convincing

⁶ As explained above, during oral argument Defendant’s counsel conceded that its indefiniteness argument is predicated on the threshold issue of whether the terms at issue are “words of degree.”

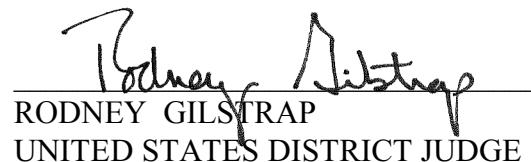
evidence that the term “with increased penetration,” and therefore that the claims in which the term appears, are invalid as indefinite.

IV. CONCLUSION

The Court finds that no construction of the disputed terms of the ‘913 patent is necessary, for the reasons set forth in this opinion. The Court further finds that the ‘913 patent claims are not invalid for indefiniteness, as set forth above.

Within thirty (30) days of the issuance of this Memorandum Opinion and Order, the parties are hereby ORDERED, in good faith, to mediate this case with the mediator agreed upon by the parties. As a part of such mediation, each party shall appear by counsel and by at least one corporate officer possessing sufficient authority and control to unilaterally make binding decisions for the corporation adequate to address any good faith offer or counteroffer of settlement that might arise during such mediation. Failure to do so shall be deemed by the Court as a failure to mediate in good faith and may subject that party to such sanctions as the Court deems appropriate.

So ORDERED and SIGNED this 23rd day of June, 2014.



RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE